
Q. What is an Emergency Use Authorization?
A: Under section 564 of the Federal Food, Drug & Cosmetic Act, the FDA may, pursuant to a determination and declaration by the HHS Secretary, authorize an unapproved product or unapproved uses of an approved product for emergency use. In issuing an EUA, the FDA must determine, among other things, that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by a chemical, biological, radiological, or nuclear agent; that the known and potential benefits outweigh the known and potential risks for the product; and that there are no adequate, approved, and available alternatives. Emergency use authorization is NOT the same as FDA approval or licensure.

Q. What does this EUA allow?
A. The EUA authorizes Veklury (remdesivir), manufactured by Gilead, for emergency use by healthcare providers to treat suspected or laboratory-confirmed coronavirus disease 2019 (COVID-19) in all hospitalized adult and pediatric patients.

Q. How is the revised EUA for Veklury (remdesivir) different than the EUA initially granted on May 1, 2020?
On May 1, 2020, FDA granted Gilead’s EUA request authorizing Veklury (remdesivir) for emergency use by licensed health care providers to treat suspected or laboratory-confirmed COVID-19 in hospitalized adult and pediatric patients with severe disease. When initially granted, the EUA limited the authorization of Veklury (remdesivir) to hospitalized adult and pediatric patients with severe disease, which was defined as patients with low blood oxygen levels or needing oxygen therapy or more intensive breathing support such as a mechanical ventilator.

On August 28, 2020, based on the totality of scientific information available, including data that have become available since the May 1 original issuance of the EUA, FDA revised the emergency use authorization (EUA) for Veklury (remdesivir) to broaden the scope of its authorized uses. Under the revised EUA, Veklury (remdesivir) is authorized for emergency use by healthcare providers for the treatment of suspected or laboratory-confirmed COVID-19 in all hospitalized adult and pediatric patients, irrespective of their severity of disease.

Q. Is Veklury (remdesivir) approved by the FDA to treat COVID-19?
A. No. Veklury (remdesivir) is an investigational antiviral drug. It is not currently FDA-approved to treat or prevent any diseases, including COVID-19.


Updated 10/6/2020
Q. Are there data showing Veklury (remdesivir) might benefit patients with COVID-19?

A. The following describes scientific information, including information and/or data from randomized, controlled trials, that FDA evaluated¹ as part of its decision to expand the Emergency Use Authorization for Veklury to include the treatment of suspected or laboratory-confirmed COVID-19 in all hospitalized adult and pediatric patients, irrespective of their severity of disease.²

In Vitro Data:

In vitro (laboratory) testing of Veklury (remdesivir) demonstrated it is active against SARS-CoV-2 (the virus causing COVID-19).

Data from Phase 3 Clinical Trials:

**NIAID ACTT-1 Trial**

One randomized, double-blind, placebo-controlled clinical trial (ACTT-1), conducted by the National Institute of Allergy and Infectious Diseases, evaluated how long it took for subjects to recover from COVID-19 within 29 days of being treated. The trial evaluated 1,062 hospitalized subjects with mild, moderate or severe COVID-19 randomized to receive Veklury (n=541) or placebo (n=521), plus standard of care. Approximately 10% of the subjects had mild to moderate disease at baseline (did not require supplemental oxygen or a ventilator or ECMO). Approximately 25% of the subjects were on a ventilator or ECMO. Recovery was defined as either being discharged from the hospital or being hospitalized but not requiring supplemental oxygen and no longer requiring ongoing medical care. The median time to recovery from COVID-19 was 10 days for the Veklury group compared to 15 days for the placebo group, a statistically significant difference. Overall, the odds of clinical improvement at Day 15 were also statistically significantly higher in the Veklury group when compared to the placebo group. This trial included a sizeable proportion of patients who were receiving mechanical ventilation or extracorporeal membrane oxygenation (ECMO) at baseline. Based on the data for these patients, the Fact Sheet for Healthcare Providers recommends a 10-day treatment course for patients receiving mechanical ventilation or ECMO. In hospitalized patients with mild to moderate disease, the results for the odds of improvement at Day 15 and the time to recovery through Day 29 were consistent with the overall study results and numerically favored Veklury.

**Gilead GS-US-540-5774 Trial**

Data from a randomized clinical trial of hospitalized patients with moderate confirmed COVID-19 disease (radiological evidence of pneumonia without an oxygen requirement during screening) compared treatment with Veklury (remdesivir) for five days (n=191) and treatment with Veklury for 10 days (n=193) with standard of care (n=200). Researchers evaluated the clinical status of subjects on Day 11. Overall, the odds of a subject’s COVID-19 symptoms improving were statistically significantly higher in the five-day Veklury group at Day 11 when compared to those receiving only standard of care. The odds of improvement with the 10-day treatment group when compared to those receiving only standard of care were statistically significantly higher.

¹ In revising the scope of the EUA for Veklury (remdesivir), the Agency determined, among other things, that, based on the totality of the scientific information available, it is reasonable to believe that Veklury may be effective for its authorized uses.

² FDA’s response has been updated with additional data and/or information obtained since FDA’s initial authorization of Veklury (remdesivir) for emergency use. For additional information, please also refer to section 18 of the Fact Sheet for Healthcare Providers for Veklury, which is available at: [https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization)

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care were numerically favorable, but not statistically significantly different. At Day 28, mortality was less than or equal to 2 percent in all treatment groups. Limitations of this trial included the open-label design.

**Gilead GS-US-540-5773 Trial**
This open-label, Phase 3 trial evaluated 5-day and 10-day dosing durations of Veklury (remdesivir) in hospitalized patients with severe COVID-19 disease. Results showed that patients receiving a 5-day treatment course demonstrated similar clinical status at Day 14 as those taking a 10-day treatment course; however, importantly, very few patients in this trial were receiving mechanical ventilation or ECMO at baseline. Therefore, based on these findings, the Fact Sheet for Health Care Providers continues to recommend a 5-day treatment course for patients who are not receiving mechanical ventilation or ECMO. Patients who receive a 5-day treatment course but do not demonstrate clinical improvement may receive Veklury (remdesivir) for an additional 5 days. Limitations of this trial included the open-label design.

**Q. Are there clinical trials underway evaluating Veklury (remdesivir) for COVID-19?**
A. Yes. [Clinical trials](#) remain ongoing to study Veklury (remdesivir) for investigational uses.

**Q. Are there side effects of Veklury (remdesivir)?**
A. Possible side effects of Veklury (remdesivir) are:

- Hypersensitivity reactions, including infusion-related and anaphylactic reactions. Hypersensitivity reactions, including infusion-related and anaphylactic reactions, have been seen during a Veklury (remdesivir) infusion or around the time Veklury (remdesivir) was given. Signs and symptoms may include: low blood pressure, high heart rate, low heart rate, shortness of breath, wheezing, swelling (e.g. lips, around the eyes, under the skin), rash, nausea, vomiting, sweating, and shivering.

- Increases in levels of liver enzymes, seen in abnormal liver blood tests. Increases in levels of liver enzymes have been seen in people who have received Veklury (remdesivir), which may be a sign of inflammation or damage to cells in the liver.

These are not all the possible side effects of Veklury (remdesivir). Veklury (remdesivir) is still being studied so it is possible that all of the risks are not known at this time.

**Q. How can Veklury (remdesivir) be obtained for use under the EUA?**
A. As of October 1, 2020, the United States Government will no longer be directing the allocation of Veklury (remdesivir) as part of the EUA. As stated in the revised [Letter of Authorization](#) for the EUA, Gilead and authorized distributors will ensure Veklury (remdesivir) is distributed to hospitals and healthcare facilities for use under the EUA. Healthcare providers interested in administering Veklury (remdesivir) should contact Gilead.

Outside of the EUA, Veklury (remdesivir) remains available through [Emergency investigational new drug applications (EINDs)](#) for pregnant women and children if they cannot gain access to Veklury (remdesivir) via the EUA.

**Q. Does the EUA permit Veklury (remdesivir) to be used outside the hospital (non-hospitalized patients)?**
A. No. Use of Veklury (remdesivir) in a non-hospital setting is outside the scope of the Emergency Use Authorization.

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Q. Is there a requirement for providers to report side effects as part of the EUA?
A. Yes. As part of the EUA, FDA is requiring health care providers who prescribe Veklury (remdesivir) to report all medication errors and serious adverse events considered to be potentially related to Veklury (remdesivir) through FDA’s MedWatch Adverse Event Reporting program. Providers can complete and submit the report online; or download and complete the form, then submit it via fax at 1-800-FDA-0178. This requirement is outlined in the EUA’s health care provider fact sheet. FDA MedWatch forms should also be provided to Gilead.

Q. Do patient outcomes need to be reported under the EUA?
A. No, reporting of patient outcomes is not required under the EUA. However, reporting of all medication errors and adverse events considered to be potentially related to Veklury (remdesivir) occurring during Veklury (remdesivir) treatment is required.

Q. Does the EUA authorize Veklury (remdesivir) to be used to prevent COVID-19?
A. No. Veklury (remdesivir) is authorized for emergency use by healthcare providers to treat suspected or laboratory-confirmed coronavirus disease 2019 (COVID-19) in hospitalized adult and pediatric patients. Use of Veklury (remdesivir) for the prevention of COVID-19 is not authorized and outside the scope of the Emergency Use Authorization.

Q. How does this EUA add to/differ from the existing Expanded Access approval?
A. An EUA is a temporary measure, pursuant to a Secretary of Health and Human Services declaration, in which the FDA Commissioner may authorize unapproved medical products or unapproved uses of approved medical products for use in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear (CBRN) threat agents. In issuing an EUA, the FDA must determine, among other things, that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by the CBRN agent; that the known and potential benefits outweigh the known and potential risks for the product; and that there are no adequate, approved, and available alternatives.

On May 1, 2020, FDA granted Gilead’s EUA request authorizing Veklury (remdesivir) for emergency use by licensed health care providers to treat suspected or laboratory-confirmed COVID-19 in adult and pediatric patients hospitalized with severe COVID-19. On August 28, 2020, FDA revised the EUA authorizing Veklury (remdesivir) for emergency use by healthcare providers to treat all hospitalized adult and pediatric patients with suspected or laboratory-confirmed COVID-19. FDA’s EUA for Veklury (remdesivir) is subject to the conditions as detailed in the letter of authorization.

While EUAs may only be issued while the Secretary of Health and Human Services declaration justifying emergency use is in effect, requests for expanded access to an investigational drug may be submitted to FDA and considered at any time. Expanded access is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. Expanded access requires submission of an expanded access protocol to an existing investigational new drug application (IND) or a new expanded access IND, and is subject to certain IND requirements, such as IND safety reporting and informed consent.

Updated 10/6/2020
For Veklury (remdesivir), the following mechanism may be available for expanded access:

- Treatment under emergency investigational new drug applications (EINDs) for pregnant women and children less than 18 years of age with confirmed COVID-19 or severe manifestations of disease if they cannot gain access to Veklury (remdesivir) via the EUA.

For more information about expanded access to Veklury (remdesivir), please contact Gilead or refer to the following webpage: Emergency Access to Veklury (remdesivir) Outside of Clinical Trials.

Q. Why has a warning about drug interactions between hydroxychloroquine sulfate/chloroquine phosphate and Veklury (remdesivir) been added to the healthcare provider Fact Sheet?
A. Laboratory testing was conducted that raised serious concerns about a risk of reduced antiviral activity for Veklury (remdesivir) when Veklury (remdesivir) is co-administered with chloroquine phosphate (CQ) or hydroxychloroquine sulfate (HCQ). This means there is the potential for Veklury (remdesivir) to not work as well to treat COVID-19 when it is taken with CQ/HCQ. Although further testing needs to be done, FDA has determined that the data are sufficient to warn health care providers, and FDA recommends against administering the drugs together.

Q. What if I take hydroxychloroquine sulfate for a chronic condition? Does this mean I should not take Veklury (remdesivir)?
A. There is the potential for Veklury (remdesivir) to not work as well to treat COVID-19 when it is taken with hydroxychloroquine sulfate (HCQ) or chloroquine phosphate (CQ). FDA recommends against taking the drugs together. If you are taking HCQ or CQ, discuss your options and specific situation with your health care provider.

Q. What is FDA doing to facilitate the development and expedite the review of Veklury (remdesivir)?
A. On March 26, 2020, FDA granted Fast Track designation to Gilead for Veklury (remdesivir), which among other things, maximizes the opportunities for Gilead to engage with the Agency on its development of remdesivir for the treatment of COVID-19.

Based on this designation, on April 6, 2020, FDA granted Gilead’s request and accepted its proposal to allow for a rolling review of its development program for Veklury (remdesivir). Under this process, Gilead could submit and FDA reviewed sections of Gilead’s New Drug Application (NDA) for Veklury (remdesivir) as they arrived. Under traditional processes, FDA’s review of an NDA does not begin until the sponsor has submitted the entire application to the Agency.


Q. Can health care providers share the patient/caregiver Fact Sheet electronically?
A. The letter of authorization for Veklury (remdesivir) requires that Fact Sheets be made available to healthcare providers and to patients/caregivers, “through appropriate means.” Electronic delivery of the Fact Sheet is an appropriate means, for example, when the patient requests it electronically, the Fact Sheet is delivered as a PDF (not a URL), and the patient is able to obtain access to the electronic version.
prior to receiving the medicine. Additionally, health care providers should confirm receipt of the fact sheet with the patient. Paper copies must be available for patients who request them.